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IN THE

Supreme Court of the United States

October Term, 1981

DARBY DRUG CO., INC., INWOOD LABORATORIES INCORPORATED, MD PHARMACEUTICAL COMPANY, INC., PREMO PHARMACEUTICAL LABORATORIES, INC., RUGBY LABORATORIES, INC., and SHERRY PHARMACEUTICAL CO., INC.,
Petitioners,

against

IVES LABORATORIES, INC.,
Respondent.

Brief *Amicus Curiae* of the Attorney General of the State of New York

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Brief *Amicus Curiae* of the Attorney General of the State of New York.

Interest of *Amicus Curiae* New York State.

The Attorney General of the State of New York submits this *amicus curiae* brief pursuant to Rule 36(4) of the Rules of this Court, since the holding of the Court of Appeals for the Second Circuit may adversely affect an important legislative policy of the State of New York.

In 1977, New York State joined a nationwide trend when it enacted its "Generic Drug Substitution Act" (L 1977, ch 776), which permits prescribing physicians to authorize pharmacists to substitute therapeutically equivalent generic drugs for their more expensive brand name counterparts.* As stated by Governor Hugh Carey in his memorandum approving this statute, its purpose is "to reduce health care costs without sacrificing quality" (New York State 1977 Legislative Annual, pp 258-9). The importance of this legislative object was recognized by the Court of Appeals for the Second Circuit in affirming denial of an injunction against implementation of the New York law:

> "* * * the local benefit is the potential saving to New York patient-consumers based on the price differentials between brand name drugs and lower-priced generic equivalents, which represents a legitimate interest. See *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council,* 425 U.S. 748, 763-64, 96 S. Ct. 1817, 48 L.Ed. 2d 346 (1976)."

Pharmaceutical Society of the State of New York v Lefkowitz, 586 F2d 953, 957 (2d Cir, 1978).

*Prior to 1972, virtually every state had a drug "anti-substitution" law which prevented pharmacists from deviating from the face of a prescription, despite the availability of less expensive generic alternatives (*Drug Product Selection,* Staff Report to the Federal Trade Commission [1979], p 150). In light of heightened Federal regulatory control over drug efficacy (see, 21 USC § 355[d], [e]), the 1970s saw a rapidly accelerating repeal of these laws and their replacement with statutes permitting drug substitution. Forty-eight states, the District of Columbia and Puerto Rico have now enacted such laws (see, Appendix A; see also, "Competition in the Drug Industry: Hearings Before the Subcom. on Oversight & Investigations," House Comm. on Energy & Commerce 13, 91st Cong, 1st Sess. (3/10/81); Warner, "Consumer Protection and Prescription Drugs: The Generic Drug Substitution Laws," 67 Ky. L.J. 384 (1978-9).

This state purpose, embodied in legislation throughout the country, is hindered by the holding of the Court of Appeals for the Second Circuit in the instant case. That Court has held that Ives Laboratories can bar generic pharmaceutical manufacturers and distributors from using the colors of its promoted brand drug, "Cyclospasmol." As found by the District Court in this matter (488 F Supp 394, 399-400 [EDNY, 1980]), this inability by generic manufacturers to use a brand name drug's accustomed color tends to confuse patients as to the content and effect of generic drugs substitutable under New York's "Generic Drug Substitution Act." This confusion increases, without any scientific basis, patient resistance to drug substitution, thus undermining the State policy seeking to promote greater use of approved substitutes to reduce drug costs. Moreover, the resultant increased sale of more expensive drugs means increased costs to the State for Medicaid payments to eligible recipients.

Summary of Argument.

The State of New York has, through its "Generic Drug Substitution Act" (L 1977, ch 776), expressed a clear policy of promoting the substitution of less expensive generic drugs which are therapeutically equivalent to brand name "reference" drugs. The Court of Appeals for the Second Circuit has inhibited this policy by holding that generic drugs cannot be marketed in the same color as their brand name counterparts. Confusion caused by the marketing of equivalent drugs with different colors increases patient resistance to the drug substitution sought to be encouraged in New York State.

Moreover, the Court of Appeals for the Second Circuit erred in basing its determination in part upon judicial notice of indictments alleging illegal drug substitution and mislabelling in New York City. These indictments do not

support that Court's holding, but indicate instead a vigorous and effective State enforcement program to protect the very interests asserted by the respondent, Ives Laboratories, Inc., in this matter.

ARGUMENT.

Preventing the use of generic drugs of the same color to which consumers were accustomed in their prior use of the brand name product interferes with a valid State policy, expressed not only in New York but by the Legislatures of 48 states.

After the trial, the District Court made the following factual findings relevant to the State's interest as described above (488 F Supp 394 [E.D.N.Y. 1980]):

1. Ives offered no proof that the generics involved had a therapeutic effect differing from that of the Ives Laboratories promoted brand, "Cyclospasmol" (*id.* at 396).

2. Under New York law, the pharmacist may properly but need not substitute the particular drug involved (*id.* at 397; see to the same effect, 638 F2d at 541, n 5).

3. Nine of ten pharmacists who used the "Cyclospasmol" name when dispensing a generic told the patients about it and only one charged a higher "brand" price (488 F Supp at 397).

4. The similarity of color is functional in that many elderly patients associate the appearance of their medication with its therapeutic effect, and others commingle drugs in a single container and rely on appearance to follow their doctors' instructions; color is also useful to

doctors and hospital emergency rooms in identifying overdoses of drugs (*id.* at 399-400).

5. There is no reason to suppose that drug color has acquired a secondary meaning, since patients, as distinct from physicians, do not associate "Cyclospasmol" with a particular manufacturer (*id.* at 400), nor was there any evidence that physicians were deceived by color identity.

These findings were supported by the record, as noted by Judge Mulligan, in his dissent in the Court of Appeals (*Ives Laboratories, Inc. v. Darby Drug Co.*, 638 F2d 538, 547 [2d Cir, 1981]). Nonetheless, the majority in the Court of Appeals found a lack of concrete evidence for the District Court's explanation that mislabelling occurs because of confusion rather than as a result of inducement (*id.* p 544).

The State of New York believes that the District Court was correct in holding that any benefit accruing from patient ease in detecting an improper drug substitution is far outweighed by the State's legitimate interest in fostering the use of generic substitutes. As noted by that Court "[t]o require different capsule colors might to some extent deter a wrongdoer but it would also severely inhibit legal substitution which the legislature deems to be in the public interest" (488 F Supp at p 401). The Court of Appeals erred in failing to take this vital public interest into account.

Moreover, the Court went on to take judicial notice of indictments handed down in the New York City area alleging illegal substitution and mislabelling of generic cyclandelate in prescriptions requiring cyclospasmol, and to hold that these indictments are inconsistent with the contention that mislabelling is rare or unintentional. The

fact is that the indictments are simply a mark of the effective Medicaid fraud enforcement program which is carried on in New York.*

New York State has adopted a systematic effort to police implementation of the drug substitution and Medicaid programs. As part of this effort, the State seeks to see that consumers obtain the benefits of the drug substitution law, including knowledge of when substitution occurs and the benefit of any lower price. This effort includes enforcement of the State's ban on misbranding and the requirement that the correct proprietary names of material prescribed be shown on labels (New York Education Law, §6815[2]). The State effort includes both reception of complaints of alleged violations and also sample purchases.

As already noted, the clear State policy of promoting substitution of equivalent generics is undermined by the holding of the Court of Appeals. But beyond that it would be extremely ironic if this Federal intrusion were justified in part by the very success of a State enforcement program designed to protect the interest asserted by Ives in the instant matter.

As a result of the State's effort, indictments have been obtained in numerous cases, some of which were cited by the Court of Appeals, as noted above, in support of its conclusion that a ban on similarity of colors of promoted and generic cyclandelate was necessary to prevent misbranding in violation of section 32 of the Lanham Trade-Mark Act, 15 USC, §1114. The conclusion of the Court of Appeals is based on the assumption that New

*The State's effective cost containment and Medicaid fraud enforcement programs have earned Federal recognition in the form of forgiveness of otherwise applicable Federal funding reductions (see New York Times, 11/8/81, p 6E).

York State's program is ineffective, for which no support in the record is cited.

There is no statutory indication that Congress authorized the Federal courts to intrude and undermine State policy in the manner mandated by the Court of Appeals, especially when, as here, Ives deliberately chose to bypass available State remedies and instead to pursue exclusively its efforts to get the Federal courts to grant it a color monopoly.

Even if a section 32 violation had been properly found, the remedy imposed by the Court of Appeals is excessive and unduly infringes on State interests. Certainly, there are less intrusive alternative remedies available to prevent deception. For example, a requirement of a logo or imprint in a contrasting color, so as to be readily visible even on the small capsule, was never considered by the Court of Appeals.

CONCLUSION.

The decision of the Court of Appeals should be reversed, and that of the District Court reinstated.

Dated: Albany, New York
November 23, 1981

Respectfully submitted,

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APPENDIX "A."

State Statute Citations—Generic Substitution Acts*

1. Alabama Code §34-23-8 (1979)

2. Alaska Stat. §08.80.295 (1976)

3. Arizona Rev. Stat. Ann. §32-1963.01 (1979)

4. Arkansas Stat. Ann. §72-1049 (1976)

5. California (Business and Professions) Code §§ 4047.6 and 4047.7 (1976)

6. Connecticut Gen. Stat. Ann. §§ 20-185a through 20-185f (1976)

7. Colorado Rev. Stat. §12-22-124 (1978)

8. Delaware Code Ann. Tit. 24, §2589 (1979)

9. Florida Stat. Ann. §465.025 (1976)

10. Georgia Code Ann. §§ 79A-408.1 through 79A-408.5 (1978)

11. Hawaii Drug Product Selection Act; Hawaii Rev. Stat. Tit. 19, §§ 328-91 through 328-99 (1979)

12. Idaho Ann. §§ 18-479-446; 17-479-460 in acc. with §37-2702(d), (1979) (see latest supplement)

13. Illinois Rev. Stat. ch 111, § 4033 (1977)

14. Indiana—none

15. Iowa Stat. Ann. §155.37 (1976)

16. Kansas Stat. Ann. §65-1637a (1979)

17. Kentucky Rev. Stat. §217.822 (1978)

18. Louisiana Rev. Stat. Ann. §37-1225 (1979)

19. Maine Rev. Stat. Ann. Tit. 32, §2806 (1979)

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*Year included is the year of passage. Reference is to the most recent volume, supplement, or pocket part.

20. Maryland (Health) Code Ann. §43-273A (1978)

21. Massachusetts Ann. Laws ch 112, §12D (Hichie/Law Co-op) (1976)

22. Michigan M.C.L.A. §333.17755 (1978)

23. Minnesota Stat. Ann. §151.21 (1975)

24. Mississippi Code Ann. §§ 75-29-701 through 75-29-709 (1979)

25. Missouri Drug Product Selection Law Mo. Ann. Stat. §338.056 (1979)

26. Montana Drug Product Selection Act; Mont. Rev. Codes Ann. Tit. 37, ch 7, §§ 501-510 (1977)

27. Nebraska Drug Product Selection; Neb. Rev. Stat. §§ 71-54.01 through 71-54.08 (1977) (found in 1980 Supp.)

28. Nevada Rev. Stat. §§ 639.2581 through 639.2599 (1979)

29. New Hampshire Rev. Stat. Ann. ch 146 §6-b (1973)

30. New Jersey Stat. Ann. §§ 24:6E-6 and 24:6E-7 (1977)

31. New Mexico Stat. Ann. §26-3-3 (1976)

32. New York—Chapter 776, Laws of 1976

33. North Carolina Gen. Stat. §90-76.1—76.6 (see 1980 Supp.) (Article 4—Pharmacy)

34. North Dakota Cent. Code §19-02.1—14.1 (1979)

35. Ohio Rev. Code Ann. §4729.38 (1978)

36. Oklahoma—none

37. Oregon Rev. Stat. §689.515 (1977)

38. Pennsylvania Stat. Ann. Tit. 35, §§ 960.1—960.7 (1976)

39. Rhode Island—Gen. Laws §5-19-38 (1976)

40. South Carolina Drug Product Selection Act of 1978 Code §§ 39-24-10 through 39-24-40

41. South Dakota—Codified Laws Ann. §§ 36-11-46.1 through 36-11-46.4 (1978)

42. Tennessee—Substitution of Equivalent Drug Product Act; Tenn. Code Ann. §39-2201 (1977)

43. Texas [Health] Code Ann. Tit. 4542, §12 (1978)

44. Utah—Generic Drug Substitution Act; Utah Code Ann. §§ 58-17-29 through 58-17-35 (1977)

45. Vermont Stat. Ann. Tit. 18, §4605 (1977)

46. Virginia Code Tit. 32.1, §§ 79-88 (1976)

47. Washington Rev. Code Ann. §§ 69.41.100 through 69.41.180 (1977)

48. West Virginia—Code §30-5-12b (1978)

49. Wisconsin—Stat. Ann. §140.90 (1976)

50. Wyoming—Generic Drug Substitution Act; Wyo. Stat. §§ 33-24-146 through 33-24-151 (1979)